Complete Summary

GUIDELINE TITLE

Society of Nuclear Medicine procedure guideline for therapy of thyroid disease with iodine-131 (sodium iodide).

BIBLIOGRAPHIC SOURCE(S)

Society of Nuclear Medicine procedure guideline for therapy of thyroid disease with iodine-131 (sodium iodide). Reston (VA): Society of Nuclear Medicine; 2002 Feb 10. 11 p. [15 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Benign conditions of the thyroid, such as:
  - Graves´ disease (toxic diffuse goiter)
  - Toxic or nontoxic nodular goiter
  - Autonomously functioning toxic or non-toxic nodules
- Thyroid cancer

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Nuclear Medicine
Radiology

INTENDED USERS

Allied Health Personnel
Physicians

GUIDELINE OBJECTIVE(S)

To assist nuclear medicine practitioners in evaluating patients for therapy with iodine-131 (I-131) sodium iodide for benign or malignant conditions of the thyroid gland, providing information for performing this treatment, understanding and evaluating the sequelae of therapy and reporting the results of therapy

TARGET POPULATION

Patients with benign or malignant conditions of the thyroid gland

INTERVENTIONS AND PRACTICES CONSIDERED

Oral administration of iodine-131 (I-131) as sodium iodide

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Relevant guidelines from other organizations were reviewed and taken into consideration. Literature searches were performed to include current scientific evidence. In addition, references known to experts and references from the nuclear medicine community were considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Drafts of the guideline were submitted to members of the Guideline Development subcommittee (methodologists) and the Task Force (subject experts). These reviewers indicated on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for all reviewers was calculated for each revision and compiled by the Society of Nuclear Medicine (SNM) central office. It is expected that the percentage of agreement will increase with each revision.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When the Task Force and Guideline Development Subcommittee completed their edits, draft procedure guidelines were distributed to the Society of Nuclear Medicine (SNM) Sample Review Group for comment. (The SNM Sample Review Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization).

The guideline was approved by the SNM Commission on Health Care Policy, the Board of Directors, and the House of Delegates.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Background Information and Definitions

A. Definitions
    1. Iodine-131 (I-131) is a beta-emitting radionuclide with a physical half-life of 8.1 days, a principal gamma ray of 364 KeV and a principal beta particle with a maximum energy of 0.61 MeV, an average energy of 0.192 MeV and a range in tissue of 0.8 mm.
    2. Therapy means the oral administration of I-131 as sodium iodide.
    3. Benign conditions mean Graves´ disease (toxic diffuse goiter), toxic or non-toxic nodular goiter and autonomously functioning toxic or non-toxic nodules.
    4. Malignant conditions include thyroid cancer that is sufficiently differentiated as to be able to synthesize thyroglobulin and, in most cases, accumulate radioiodine.

B. Background

Oral administration of I-131 has been a commonly accepted procedure for treatment of benign and malignant conditions of the thyroid since the 1940's. Physicians responsible for treating such patients should have an understanding of the clinical pathophysiology and natural history of the disease processes, should be familiar with alternate forms of therapy and should be able to collaborate closely with other physician(s) involved in the management of the patient´s condition. The treating physician should either see patients in consultation with the physician assuming overall management of the patient´s condition or be prepared to assume that role. In the United States, the treating physician should be board certified in Nuclear Medicine, Radiology or Radiation Oncology, or be able to document equivalent training, competency and experience in the safe use and administration of therapeutic amounts of I-131. In Europe, the treating physician should be board certified in Nuclear Medicine or Radiation Oncology.

Licensure to possess I-131 and regulations regarding the release of patients treated with radioiodine vary from jurisdiction to jurisdiction. Physicians engaged in therapy with I-31 must be knowledgeable about and in compliance with all applicable laws and regulations.

The facility in which treatment is performed must have appropriate personnel, radiation safety equipment, and procedures available for waste handling and disposal, monitoring personnel for accidental contamination and controlling spread of volatilized I-131.

Common Indications

A. Benign disease
    1. Hyperthyroidism

Iodine-131 may be indicated for the treatment of Graves´ disease, toxic multinodular goiter or toxic autonomously functioning thyroid nodule(s).

2. Non-toxic multinodular/diffuse goiter

   Iodine-131 therapy has been used successfully to diminish the size of non-toxic multinodular/diffuse goiters.

B. Thyroid cancer
   1. Post operative ablation of thyroid remnant (s) after thyroidectomy.
   2. Treatment of residual thyroid cancer and metastatic disease after partial or complete thyroidectomy.

Procedure

The detailed procedure recommendations in the original guideline document address the following areas: patient preparation; information pertinent to performing the procedure (i.e., data that the physician should have about the patient at the time the exam is performed and interpreted); precautions; information regarding the radiopharmaceutical (i.e., ranges of administered activity, organ receiving the largest radiation dose, effective dose); reporting to the referring physician.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence for the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate evaluation of patients for iodine-131 (I-131) therapy of thyroid diseases
- Appropriate and safe use of therapeutic I-131 in patients with thyroid disease

POTENTIAL HARMS

- In patients with hyperthyroidism and non-toxic multinodular goiter, iodine 131 (I-131) therapy can cause radiation thyroiditis with release of stored thyroid hormone into the circulation resulting in occasional worsening of hyperthyroidism and rarely, precipitation of thyroid storm. The risk of eventual hypothyroidism is high, especially after treatment of Graves'

disease, and lifelong ingestion of a thyroid hormone tablet would then be necessary. Ophthalmopathy may worsen or develop after I-131 therapy.

- In patients with thyroid cancer, early side effects of I-131 may include nausea, occasional vomiting, pain and tenderness in the salivary glands, loss of saliva or taste, neck pain and swelling if a sizeable thyroid remnant remains after surgery and decrease in white blood cells which may result in increased susceptibility for infection. Generally these side effects are temporary. Late side effects may include temporary infertility [in men this can be permanent as dosages progressively exceed 11.1 GBq (300 mCi)], rarely permanent damage to the salivary glands resulting in loss of saliva or stones, excessive dental caries, reduced taste, and the very rare development of other cancers including stomach, bladder, colon, salivary glands, and leukemia (only with very high cumulative doses). These late side effects are rarely seen and should not deter one from taking I-131 for treatment of their thyroid cancer.
- There is a general risk of radiation exposure to family members and members of the public; therefore, patients require instruction on how to reduce any unnecessary exposure.
- There is a general risk for accidental contamination of medical personnel when handling I-131.

Subgroups Most Likely to be Harmed:

Patients with large, iodine-avid multinodular glands who are given larger amounts of iodine-131 (I-131) are more likely to experience radiation thyroiditis with release of stored thyroid hormone into the circulation resulting in occasional worsening of hyperthyroidism and rarely, precipitation of thyroid storm.

CONTRAINDICATIONS

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I-131 therapy is contraindicated in pregnant and breast feeding/lactating women.

QUALIFYING STATEMENTS

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- The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.
- Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Society of Nuclear Medicine procedure guideline for therapy of thyroid disease with iodine-131 (sodium iodide). Reston (VA): Society of Nuclear Medicine; 2002 Feb 10. 11 p. [15 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Feb 10

GUIDELINE DEVELOPER(S)

Society of Nuclear Medicine, Inc - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Nuclear Medicine (SNM)

GUIDELINE COMMITTEE

Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Society of Nuclear Medicine. Procedure guideline for guideline development. Reston (VA): Society of Nuclear Medicine; 2001 Jun (version 3.0).

  Electronic copies: Available from the Society of Nuclear Medicine Web site.

- Society of Nuclear Medicine. Performance and responsibility guidelines for NMT. Reston (VA): Society of Nuclear Medicine; 2003.

  Electronic copies: Available from the Society of Nuclear Medicine Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 6, 2002. It was verified by the guideline developer as of September 10, 2002.

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Date Modified: 11/8/2004